



# **Biotechnology Industry**

## **Code of Conduct**

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\*The basic principle of this Code is that on becoming a Member of AusBiotech, companies and individuals would agree, as part of their Membership Application to adopt the Code of Conduct in their working practices.

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## 1. About the Code of Conduct

The Scope of the AusBiotech Code of Conduct is to:

- Provide a set of guidelines and principles for Members of AusBiotech with a broader flow-on effect to biotechnology stakeholders;
- Provide a public communication document about the code of conduct adhered to in biotechnology research and development; and
- Provide an all-of-industry and all-of-government approach to responsible practice.

AusBiotech utilises the following definition of biotechnology.

*"The application of all natural sciences and engineering to the direct or indirect use of living organisms or parts of organisms, in their natural or modified forms, in an innovative manner in the production of goods and services (including, for example, therapeutics, foodstuffs, medical devices, diagnostics, bioinformatics, nanotechnology etc.) and/or to improve existing industrial processes. Market application of outputs is typically in the general areas of human health, food production, industrial bio-processing, and other public good and environmental settings."*

The Code of Conduct is applicable to all areas covered under AusBiotech's definition of biotechnology.

Separate sections (section 5-7) have been provided for focus sector areas of human health, medical devices and agricultural biotechnology, to address specific elements relevant to these industries and not specifically described under the broader code of conduct.

## 2. AusBiotech's Responsibility to Members

### Mission

*AusBiotech's Mission is to foster an appropriate environment to enable companies to grow, advance their commercial interests and assist them to become global, thereby positioning Australia's biotechnology industry as a significant market for attracting international interest and investment.*

*AusBiotech will achieve its Mission by advancing the interest of Members through the provision of policy development and implementation, advocacy, networking, advice, education, relevant services and international out-reach at a level consistent with being the "Peak Industry Body".*

### Vision

*AusBiotech's Vision is to be the recognised, respected and acknowledged leader of the Australian Biotechnology Industry by successfully fostering the growth and globalisation of companies and the Australian biotechnology industry".*

*AusBiotech's Vision will be achieved by representing Members across all sectors of biotechnology whilst being financially sustainable, independent of government funding, and employing staff specialising in key areas of policy development and implementation, advocacy, regulatory affairs, finance, marketing, public relations, business development, and commercialisation.*

AusBiotech, as the peak biotechnology industry organisation in Australia, representing over 2,400 Members, has the following objectives and responsibilities to its Members:

- To represent the interests and views of AusBiotech Members and make submissions and recommendations to state and federal governments, enquires, regulatory authorities, media and professionals on important issues and to provide industry views and comments that will support, explain and benefit the Australian biotechnology industry;
- To promote the recognition of biotechnology as an important and ethical industry, which is worthy of community and investor support;
- To provide a mechanism for the ongoing review and discussion of the development and commercialisation of biotechnology in Australia;
- To promote national interests and provide forums for the exchange of ideas and views amongst Members and the business, policy and scientific communities at large;

- To assist Members to develop their skills and remain up to date on issues relating to the biotechnology industry and their ongoing success and sustainability;
- To promote the national and global benefits of Australian biotechnology; and
- To collect and distribute information with respect to biotechnology in Australia.

### **3. Member Commitments to the Industry**

- Members are to act in the best interest of the Australian biotechnology sector;
- Members are to act at all times with integrity and honesty;
- Members will adhere to regulatory and statutory laws governing biotechnology in Australia;
- Members may advertise their Membership of AusBiotech when promoting their services, through the use of the phrase 'Member of AusBiotech';
- Members will respect intellectual property rights and confidential business information gained in the conduct of their professional activities;
- Members are committed to transparency of operations and open communications with employees and the public on relevant biotechnology issues;
- Members will develop training and information programs for their employees to ensure they have access to the most up to date information;
- Members will only publish or issue information, claims, or graphical representations that are an accurate record of soundly based observation, experimentation, or are otherwise clearly identified as an opinion;
- Members will ensure that staff and colleagues are made aware of this Code of Conduct and other standards, guidelines and laws relevant to the safe and ethical conduct of biotechnology activities;
- Members are not to engage in practices restricted by law or professional agreement;
- Members are to avoid unwarranted statements that reflect upon the character or integrity of other Members or knowingly do or cause any activity that reflects badly upon AusBiotech or the industry without verifiable cause;
- Members are to recognise their responsibility to the community and the environment and protect each from exposure to actual or potential hazards;
- Members shall not make any public statements purporting to be the policy of the AusBiotech when this is not the case;
- A Member shall at all times in the course of their professional activities consider a person's individual merit and standing over and above characteristics of age, race, religious belief, sexual preference, cultural or ethnic background, and shall encourage this behaviour in colleagues;

- A Member will inform their employer or client if circumstances arise in which their judgment or advice may be called into question due to a conflict of interest or for any reason of business connections, personal relationships, interests, or affiliation; and
- Members are requested to comply with the spirit of this Code of Conduct.

*Member companies also recognise AusBiotech's responsibility to consider deviations by its Members from the Code of Conduct and to recommend appropriate responses after a reasonable due process.*

## **4. AusBiotech Code of Conduct**

### **Overview**

AusBiotech is committed to the socially responsible use of biotechnology in health care, food and agriculture, medical devices and diagnostics, industry and the environment.

As biotechnology reaches towards delivering national and global benefits, such as treatments for intractable diseases; abundant, nutritious food; industrial sustainability; and a cleaner world, AusBiotech encourages public discussion of the ethical, legal and social implications of biotechnology research.

The biotechnology industry recognises its responsibility to encourage, through dialogue and education, a better mutual understanding of ethical concerns. These concerns include any cultural or religious aspects, related to biotechnology, possible environmental impacts, and the adequacy of regulations.

As scientists, business people and citizens, we must address questions and controversies surrounding the use of biotechnology and make choices that will best serve humanity.

Life sciences and biotechnology have given rise to significant public attention and debate. Public debate remains of central importance. Consequently, it is a core principle that promoting dialogue among stakeholders and organising public debates will accompany and guide the development of life sciences and biotechnology and ensure effective, credible and responsible policies that are in harmony with societal values.

### **Code of Conduct**

1. Realising the potential of biotechnology to improve the quality of human life and improvement in the environment;
2. Recognising the need for health, safety, and environmental protection when undertaking the research, development, manufacture and distribution of our products and services;
3. Acknowledging the power of biotechnology and its development and use with full respect for human dignity and human and animal rights;
4. Communicating and sharing information about biotechnology and its derived products and services in a balanced manner, stating both benefits and risks while listening carefully to those who are concerned about the implications of biotechnology and responding to their concerns;



5. Treating animals in a respectful manner and, when at all possible, limiting their use in research with any disproportionate suffering to animals involved in biotechnology research and/or other parts of industry work avoided to ensure the highest standards of well-being are maintained;
6. Supporting strong protection of the confidentiality of medical information, including genetic information and adhering to strict informed consent procedures;
7. Supporting the conservation of biological diversity;
8. Ensuring that all transport of biological materials comply with relevant international, national and state guidelines for safety in transport and that all exportation and importation of products or materials will comply with national standards of the Australian Quarantine and Inspection Service (AQIS) and Australian Customs Service (ACS);
9. Avoiding conduct that will damage Australia's standing internationally, and observe all relevant obligations and standards of other countries where the industry is involved in biotechnology research, development or export;
10. Opposing the use of biotechnology to develop or produce any biological or other weapons;
11. Opposing the use of human cloning;
12. Fostering the need for uniform, national and stringent regulation to assist in the development of this technology towards the benefit of society and the environment with appropriate regulation of biotechnology solidly based on values such as autonomy, privacy, beneficence, social justice and intellectual freedom;
13. Fostering dialogue that is inclusive, comprehensive, well informed, and structured. Relevant public information is essential for meaningful dialogue. It is of key importance to support information and dialogue to help the public and stakeholders better understand and appreciate these complex technologies; and
14. Acknowledging the specific requirements of the sectors of Human Health, Agriculture and Medical Devices, as outlined in sections 5-7 of this document.

Since biotechnology is innovative and rapidly developing, the Code of Conduct will be continually updated to address new issues and new insights that arise in the future.

***\*Note** - AusBiotech represents core focus sector areas. This section of the Code of Conduct builds upon the principles outlined, to provide specific statements in the areas of Human Health, Agricultural Biotech and Medical Devices. Over time, additional sector areas may also be included, to accommodate specific focus needs.*

## 5. Human Health and Medicinals

In relation to Human Health and Medicinals, AusBiotech is committed to:

1. Respecting the codes of ethics of the healthcare professionals who diagnose and treat disease, and who prescribe, dispense, and use biotechnology products or make use of biotechnology services whether in research, development or patient care;
2. Supporting the protection of the confidentiality of medical information, which includes genetic information and opposing the disclosure of such information without informed consent, which could lead to intolerance or stigmatisation;
3. Encouraging quality processes to ensure that the informed consent is obtained of all individuals participating in biotechnology research programs, taking genetic tests or undergoing medical treatment. When individuals are unable to give their consent, it is obtained from their legal representatives according to current legislative requirements;
4. Opposing the use of cloning technologies to reproduce human beings;
5. Encouraging the accessibility of counselling for genetic testing;
6. Encouraging the provisions of medicines that conform to the highest standards of safety, efficacy, and quality and comply to requirements under the Therapeutic Goods Administration (TGA);
7. Fostering that medicines are supported by comprehensive technical and informational services in accordance with current accepted medical and scientific knowledge and experience;
8. Encouraging the use of professionalism in dealing with healthcare professionals, public health officials, and the general public; and
9. Encouraging that all research involving humans is conducted under relevant guidelines and ethical practices, with review and approval to ensure standards of safety, dignity and compliance.

## 6. Agriculture, Food and Environment

In relation to Agriculture, Food and the Environment, AusBiotech is committed to:

1. Supporting and encouraging biotechnology to be recognised as the driving force behind a productive, environmentally sustainable and socially responsible agricultural value-chain today and in the future;
2. Supporting improvements in the quality of food and agricultural products, in order to enhance the world's food supply and thereby human and animal nutrition;
3. Fostering the principle that food products meet the highest standards and benefit for consumers;
4. Promoting the development of agricultural products to enhance sustainable agriculture and provide environmental benefits, ensuring that products do not adversely impact genetic diversity and the uniqueness of Australia's environment;
5. Promoting the efficient and sustainable agriculture and support new biotechnological developments, which offer additional opportunities for farmers to protect or improve their crops and to use natural resources more effectively;
6. Supporting the transparent product information to promote informed consumer choice;
7. Supporting the development of bioremediation and cleaner industrial and municipal processes through biotechnology and work to ensure that none of these processes pose unacceptable risks to human health or the environment;
8. Supporting the development of Genetically Modified (GM) agriculture assessed on a case-by-case basis by properly constituted federal regulatory agencies such as the Office of the Gene Technology Regulator (OGTR), Food Standards Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medical Authority (APVMA), Therapeutics Good Administration (TGA) and the Australian Quarantine Inspection Services (AQIS);
9. Fostering and encouraging quality investigations to ensure that plants, animals and other organisms produced do not present unacceptable risks when grown or utilised in the environment;
10. Supporting the strict regulatory risk management plans and guidelines to ensure compliance will all relevant conditions established by the Gene Technology Regulator (OGTR);

11. Fostering and encouraging quality processes to ensure that all proposed work involving genetic modification in animals is referred to, and approved by, the relevant regulatory and ethical committees and that all information and monitoring will be reported to the relevant authorities as necessary and appropriate;
12. Acknowledging that foods produced using gene technology, and sold in Australia, will be labelled where the food contains novel DNA or protein or has altered characteristics and encouraging compliance with authorities on these compliance and testing requirements for food labelling; and
13. Fostering and encouraging quality processes that any agricultural or veterinary chemicals produced through biotechnology are submitted to the National Registration Authority (NRA) for assessment, approval and registration.

## **7. Medical Devices and Diagnostics**

In relation to Medical Devices and Diagnostics, AusBiotech is committed to:

1. Respecting the codes of ethics of the healthcare professionals who diagnose and treat disease, and who make use our products or make use of our services whether in research, development or patient care;
2. Encouraging quality processes that ensure the informed consent of all individuals participating in our research programs, taking genetic tests or undergoing medical treatment is obtained;
3. Supporting the principle that devices conform to the highest standards of safety, efficacy, and quality and comply to requirements under the Therapeutic Goods Administration (TGA);
4. Encouraging quality processes that ensure devices are supported by comprehensive technical and informational services in accordance with current accepted medical and scientific knowledge and experience;
5. Supporting the use professionalism in dealing with healthcare professionals, public health officials, and the general public; and
6. Fostering and encouraging processes that ensure all research involving humans is conducted under relevant guidelines and ethical practices, with review and approval to ensure standards of safety, dignity and compliance.